

Message

---

**From:** Zborowsky, Ashley [Ashley.Zborowsky@fda.hhs.gov]  
**Sent:** 2/17/2017 7:59:34 PM  
**To:** Nalubola, Ritu [Ritu.Nalubola@fda.hhs.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Epstein, Laura [Laura.Epstein@fda.hhs.gov]; Flamm, Eric [Eric.Flamm@fda.hhs.gov]  
**CC:** Keigwin, Richard [Keigwin.Richard@epa.gov]; Layne, Arnold [Layne.Arnold@epa.gov]; McNally, Robert [McNally.Robert@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; Leahy, John [Leahy.John@epa.gov]; Wozniak, Chris [wozniak.chris@epa.gov]; Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Kaczmarek, Chris [Kaczmarek.Chris@epa.gov]; Wakefield, Benjamin J. [wakefield.benjamin@epa.gov]; Reynolds, Alan [Reynolds.Alan@epa.gov]  
**Subject:** RE: Call with Keith Matthews and Jack Bobo Regarding Oxitec's GE Mosquitoes

Hi all,

I spoke with Deepti Kulkarni of Sidley Austin this afternoon. She had already heard a recap of the discussion with EPA from Keith Matthews and indicated that Intrexon seemed pleased with the EUP option. We talked briefly about the possibility of a trial under an INAD but noted the downside with respect to preparation of an EA (at some point) and agreed that an EUP makes the most sense. She expressed some concern with respect to how FDA would announce its intent to exercise enforcement discretion and timing of final GFI 236. In particular, she wondered what would happen if EPA issued an EUP and published the FR notice before GFI 236 is final (i.e., what is the litigation risk and could this put a hold on any releases). Something to consider as far as timing, to the extent FDA is able to fast track the guidance. Lastly, she expressed her gratitude (to Ben and Chris in particular) for making this possible and to both agencies for their quick work over the last few weeks.

Best,  
Ashley

---

**From:** Nalubola, Ritu  
**Sent:** Friday, February 17, 2017 12:18 PM  
**To:** Mendelsohn, Mike; Zborowsky, Ashley; Epstein, Laura; Flamm, Eric  
**Cc:** Keigwin, Richard; Layne, Arnold; McNally, Robert; Hartman, Mark; Leahy, John; Wozniak, Chris; Milewski, Elizabeth; Kaczmarek, Chris; Wakefield, Benjamin J.; Reynolds, Alan  
**Subject:** Re: Call with Keith Matthews and Jack Bobo Regarding Oxitec's GE Mosquitoes

Thanks, Mike! Looping in Ashley and others.  
Ritu

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

---

**From:** Mendelsohn, Mike  
**Sent:** Friday, February 17, 2017 11:15 AM  
**To:** Nalubola, Ritu  
**Cc:** Keigwin, Richard; Layne, Arnold; McNally, Robert; Hartman, Mark; Leahy, John; Wozniak, Chris; Milewski, Elizabeth; Kaczmarek, Chris; Wakefield, Benjamin J.; Reynolds, Alan  
**Subject:** Call with Keith Matthews and Jack Bobo Regarding Oxitec's GE Mosquitoes

Ritu,

Chris Kaczmarek, Ben Wakefield, Elizabeth Milewski, and I talked with Keith Matthews and Jack Bobo this morning regarding Oxitec and their GE mosquitoes this morning. Consistent with our recent communication with FDA, we told them:

- 1) EPA has determined that Oxitec can immediately proceed with an experimental use permit application involving their GE mosquitoes and that EPA could issue the EUP before 236 is finalized.
- 2) EPA has determined a Section 18 involving Oxitec's GE mosquitoes can immediately be submitted and EPA can begin review, but 236 would have to be final before EPA grants the Section 18.
- 3) EPA and FDA are ready to have a joint meeting with Oxitec as soon as the firm is available to discuss additional details and EPA-FDA intersects.

Keith and Jack expressed appreciation and were pleased with the new information. Keith and Jack committed to get back with us on possible joint meeting dates with EPA and FDA and also understand that FDA will be reaching out to Oxitec as well.

Mike Mendelsohn, Acting Chief  
Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue NW  
Washington DC 20460  
(703) 308-8715  
(703) 463-7302 Mobile